PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing: 25 November 1999 (25.11.99)	
International application No.: PCT/JP99/02600	Applicant's or agent's file reference: YCT-413
International filing date: 19 May 1999 (19.05.99)	Priority date: 20 May 1998 (20.05.98)
Applicant: TAMURA, Tatsuya et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International preliminary Examining Authority on:

19 May 1999 (19.05.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
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13T

Translation

PATENT COOPERATION TREATY 09/700879

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference YCT-413	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP99/02600	International filing date (*day/month/year*) 19 May 1999 (19.05.99)	Priority date (*day/month/year*) 20 May 1998 (20.05.98)
International Patent Classification (IPC) or national classification and IPC A61K 31/728, C08B 37/08, A61K 45/00, A61P 19/02 // (A61K31/725, 31:40)		
Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19 May 1999 (19.05.99)	12 May 2000 (12.05.2000)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP99/02600

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-4,6-8,10-14,16-42, as originally filed
pages _____, filed with the demand
pages 5,9,9/1,15, filed with the letter of 17 September 1999 (17.09.1999)

☒ the claims:

pages 1, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 2-19, filed with the letter of 17 September 1999 (17.09.1999)

☒ the drawings:

pages 1-10, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 19

because:

☒ the said international application, or the said claims Nos. 19 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject matter of claim 19 relates to a method for treatment of the human body by therapy, which does not require a preliminary examination by this International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2-13	YES
	Claims	1,14-18	NO
Inventive step (IS)	Claims		YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations

Document 1 [JP, 62-64802, A (Fidia S.p.A.), 23 March, 1987 (23.03.87); & EP, 216453, A & US, 4851521, A & US, 4965353, A & US, 5202431, A & US, 5336767, A; the claims; page 10, upper right column, line 11 to page 11, upper right column, line 20; page 18, upper left column, line 19 to page 20, lower left column, line 16; working examples 10-21] discloses bound products in which something like cortisone or Tiaramide that can be used in a remedy for joint diseases is bound to hyaluronic acid, medicinal drugs that contain said bound products, and a use justifying the manufacture of said medicinal drugs. Document 2 [Search for an artificial lubricant for joints based on complexes of poly(vinyl chloride) with hyaluronic acid biopolymers, (Vasilionkaitis, V.), Sint. Izuch. Fiziol. Akt. Veshchestv, Tezisy Dokl. Mezhvuz Nauchn. Konf. Uchastiem Farmakol. Latv. Est. SSR (Publisher: Vil'nyus Gos. Univ., Vilnius, USSR), 1975, 20-1; & Abstract no. 99131, Chem. Abstr. (Columbus, OH, USA), 1976, Vol. 85; see entire document] discloses the fact that polyvinylpyrolidone has therapeutic effects against joint diseases, a bound product in which polyvinylpyrolidone is bound to hyaluronic acid, a remedy for joint diseases that contains said bound product, and a use justifying the manufacture of said remedy. The subject matter of claims 1 and 14-18 is thus considered not to be novel.

Documents 1 and 2 do not contain any disclosures relating to the subject matter of claims 2-13, namely a bound product for which the binding is by means of covalent bonding, a bound product for which the remedy for joint diseases is a cyclooxygenase-2 inhibitor, an anti-rheumatic drug or a matrix metalloprotease inhibitor, and a bound product for which said matrix metalloprotease inhibitor is bound to hyaluronic acid via a spacer. Nevertheless, it is considered that selecting covalent bonding as the type of binding in a bound product is something that could be achieved by a person skilled in the art as required; moreover, document 3 [JP, 9-501183, A (Glycomed Inc.), 4 February, 1997 (04.02.97); & WO, 95/199965, A1 & EP, 690841, A & US, 5773438, A & US, 5892112, A; see entire document] discloses matrix metalloprotease inhibitors as remedies for joint diseases, document 4 [US, 5620999, A (KHANNA, Ish K. et al.), 1 April, 1997 (01.04.97); & WO, 96/03387, A1 & EP, 772601, A1; see] column 3, lines 7-36; column 99] discloses cyclooxygenase-2 inhibitors as remedies for joint diseases, and document 5 [Risks and Benefits of Low-Dosage Cyclosporin in Rheumatoid Arthritis, (PASERO, Giampiero et al.), BioDrugs, 1997, Vol. 7, No. 5, pages 376-385; see entire document] and document 6 [Methotrexate in Rheumatoid Arthritis, (MORGAN, Sarah L. et al.), 1997, Vol. 8, No. 3, pages 164-175; see entire document] disclose anti-rheumatic drugs as remedies for joint diseases. It is thus considered that, in the case of the bound products disclosed in documents 1 and 2 in which a remedy for joint diseases is bound to hyaluronic acid, it would be easy for a person skilled in the art to conceive of using one of the cyclooxygenase-2 inhibitors, anti-rheumatic drugs or matrix metalloprotease inhibitors disclosed in documents 3-6 as the remedy for joint diseases in place of that disclosed in document 1 or 2. Moreover, it is considered that it would be easy for a person skilled in the art to conceive of taking, as a spacer, part of one of the compounds used in the matrix metalloprotease inhibitors disclosed in document 3 other than the basic skeleton central to the compound's matrix metalloprotease inhibiting activity, and

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V (Citations and explanations):

then using this spacer for binding the compound to hyaluronic acid. The subject matter of claims 2-13 is thus considered not to involve an inventive step.